Update on Revised United States Public Health Service (USPHS) Policy on HIV Screening of Pregnant Women and Treatment of HIV-Infected Pregnant Women — Martha Rogers, CDC

Good morning. The national guidelines for prevention of perinatal transmission are actually in two different documents; both are part of the MMWR Recommendations and Report series: guidelines for counseling and HIV testing of pregnant women, last published in 1995, and prophylactic treatment for women who test positive during pregnancy, second revision in 1998. Both are currently undergoing yet another revision; neither is out yet. So my talk will be in generalities.

I will begin by giving you some history about the screening of pregnant women, pointing out the evolution of policy over time.

Evolution of Policy for HIV Screening of Pregnant Women

1985—An HIV antibody test became available. CDC published the first recommendations for prevention of perinatal HIV transmission. We knew very little at that time about transmission and had little to offer pregnant women. Recommendations at that time were targeted and not very effective.

- Counseling and testing should be offered to women at high risk.
- HIV-infected women "should be advised to consider delaying pregnancy until more is known" and advised against breastfeeding.

1994—Pediatric AIDS Clinical Trials Group (PACTG) 076 results were announced. USPHS published recommendations for prophylactic treatment of HIV-infected pregnant women.

1995— USPHS published revised recommendations for HIV counseling and voluntary testing of pregnant women. The recommendation moved away from a targeted approach and more toward a universal approach, recommending that "health care providers ensure that all pregnant women are counseled and encouraged to be tested for HIV . . ." and that testing should be voluntary, not mandatory.

1996—Combination therapy with protease inhibitors became widely available and had a tremendous effect on quality of life for infected persons.

1998—USPHS published revised prophylactic treatment guidelines for use of antiretroviral (ARV) agents (including combination therapy) during pregnancy for maternal health and reduction of perinatal transmission of HIV.

1999—As a result of being commissioned by Congress (as part of the last Ryan White reauthorization) to evaluate how well CDC and other federal agencies and state health departments were doing in reduction of perinatal HIV transmission, the Institute of Medicine (IOM) published a report recommending a "national policy of universal HIV testing, with patient notification, as a routine component of prenatal care." Consent was also simplified to an opt-out or right-of-refusal approach. New findings about short-course therapy and therapy at the time of labor and delivery and to the newborn added support to the treatment recommendations.

2000—USPHS plans to publish revised guidelines for HIV screening of pregnant women and for treatment.

Controversies Around Policy for HIV Screening of Pregnant Women

- Pregnant women and newborns are often considered "vulnerable" populations, especially in terms of research and medical procedures.
- There used to be a conflict between women's rights and infant's rights, when testing was considered good for the infant but not necessarily good for the woman. However, new treatment options are enhancing the testing benefits for both.
- Policy was sometimes seen to be disrespectful and demeaning of women by treating them as vessels for reproduction and vectors for transmission. A lot of attention was needed to balance the benefits to the woman as well as to the infant.
- Financing and cost-effectiveness was a big issue, especially for low-prevalence areas. This concern may still exist.
- Changes in the informed consent process for HIV testing have raised concern that the consent process is "eroding." The move toward right of refusal may mean that women get less counseling and are less aware of some of the risks. However, benefits have greatly increased but must still be weighed against the risks.
- The IOM request for simplification of counseling has raised concern over the role of counseling: Where does counseling fit in? How long should it be? Who should deliver it? How should it be delivered?

New Advances in Science and Technology Since Publication of Original Guidelines

- More effective treatment for infected persons
- Proven effective prophylactic therapy for women at the time of delivery
- Increasing evidence for effectiveness of postexposure prophylaxis, especially with newborns
- Improved testing technology (e.g., rapid tests)
- Several studies indicating that women with undetectable viral loads transmit very rarely
- Better protection against discrimination (e.g., Americans with Disabilities Act)

Lessons Learned from Evaluation of Current Policy and Putting Programs into Place

- Testing is highly accepted when strongly recommended by provider.
- Lack of prenatal care is a big problem, especially among substance-abusing women.
- Some women decline testing, and some providers decline to offer testing because they perceive low risk.
- Logistics may sometimes be a problem.
- Adherence to complex treatment regimens can be difficult.
- IOM finds that some providers perceive counseling as a barrier to providing testing.

Themes and Directions for Revised Guidelines

- Emphasis will be on testing as a routine part of prenatal care.
- The testing process will be simplified (with the provision of minimal information).

- More extensive counseling ("prevention counseling") is not necessarily linked to testing but is recommended as part of routine education of pregnant women.
- Testing remains voluntary, but right-of-refusal type of consent is permitted.
- The consent process is flexible by permitting right of refusal but not recommending against more traditional informed consent. Written consent will not be mandatory in the new guidelines, although some state laws still require it. Ideally, HIV testing would be more like other prenatal disease screening.
- Providers should explore and address reasons for refusal of testing.
- More emphasis should be placed on testing and treatment at time of delivery for women without prenatal care.
- Testing of the newborn is recommended if the mother has not been tested, but testing is not mandatory if the mother refuses.

Update on Prophylactic Treatment Recommendations and Other Interventions

- The last document (published in 1998) took combination therapy into consideration.
- Other adult and pediatric treatment guidelines are dynamic documents and are maintained on the internet.
- An expert panel was formed in December 1999 to revise prophylactic treatment guidelines for pregnant women.
- This dynamic document will be available on the internet sometime in 2000.
- Immediate issues to be addressed by the panel:
    - What is the best treatment at time of delivery for women without prenatal care? Nevirapine? Zidovudine? Combination therapy? Other drugs?
    - What should mode-of-delivery recommendations be? We need to explore the value of cesarean delivery in women with very low viral loads.

Remaining Issues for Consideration

- ARV toxicity and long-term effects on children
- Need for more licensed rapid tests. Need two rapid tests to approximate the reliability of enzyme-linked immunosorbent assay and Western blot tests.
- Mode of delivery recommendations
- Treatment at time of delivery recommendations
- New Ryan White authorization around perinatal HIV transmission

Again, the themes, especially around counseling and testing and screening, are in draft form and may vary in final form.

Contact Information

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